217/782-2113

CONSTRUCTION PERMIT NESHAP SOURCE - REVISED

PERMITTEE

Abbott Laboratories
Attn: Daniel J. Wozniak, Air Manager, Lake County EH&S
1401 Sheridan Road D72N/P14
North Chicago, Illinois 60048-4000

Application No.: 01070032 I.D. No.: 097125AAA
Applicant's Designation: PC 830 Date Received: March 28, 2003
Operation of: Pharmaceutical Manufacturing Plant
Date Issued: April 11, 2003
Source Location: 1401 Sheridan Road, North Chicago, Lake County

This Permit is hereby granted to the above-designated Permittee to CONSTRUCT emissions source(s) and/or air pollution control equipment consisting of a replacement reactor PC830 as described in the above-referenced application. This Permit is subject to standard conditions attacked hereto and the following special condition(s):

1.0 Unit Specific Conditions

1.1 1,500 Gallon Reactor

1.1.1 Description

The equipment in Building C-10 is used to produce a wide variety of pharmaceutical and pharmaceutical-like products via batch chemical processing techniques, termed Chemical Manufacturing by the source.

1.1.2 List of Emission Units and Pollution Control Equipment

Emission Unit	Description	Emission Control Equipment
LC989905	1,500 Gallon Reactor (Reactor 830, PC-830)	PC-828 Vacuum System, VS-601 Surge Tank and PC-839 Scrubber, Various Control Equipment, CMA Thermal Oxidizer 1 and 2 Systems

1.1.3 Applicability Provisions and Applicable Regulations

a. The Building C-10 process reactors are "affected chemical manufacturing units" for the purpose of these unit-specific conditions.

b. Each affected chemical manufacturing unit is subject to the emission limits identified in Condition 5.2.2 of the sources Title V permit.

c. The affected chemical manufacturing units are subject to the NESHAP for Pharmaceuticals Production, 40 CFR 63 Subparts A and GGG. The Illinois EPA is administering the NESHAP in Illinois on behalf of the USEPA under a delegation agreement.

d. The affected chemical manufacturing units are subject to 35 IAC 218 Subpart G, Use of Organic Material, which provides that:

i. No person shall cause or allow the discharge of more than 3.6 kg/hr (8 lb/hr) of organic material into the atmosphere from any emission unit, except as provided in Condition 1.1.3 (d)(ii) (See also 35 IAC 218.302) and the following exception: If no odor nuisance exists the limitation of 35 IAC 218 Subpart G shall apply only to photochemically reactive material [35 IAC 218.301].

ii. Pursuant to 35 IAC 218.302, emissions of organic material in excess of those permitted by Condition 1.1.3(d)(i) (See also 35 IAC 218.301) are allowable if such emissions are controlled by one of the following methods:

A. A vapor recovery system which adsorbs and/or condenses at least 85 percent of the total uncontrolled organic material that would otherwise be emitted to the atmosphere [35 IAC 218.302(b)]; or

B. Any other air pollution control equipment approved by the Illinois EPA and approved by the USEPA as a SIP revision capable of reducing by 85 percent or more the uncontrolled organic material that would be otherwise emitted to the atmosphere [35 IAC 218.302(c)].

1.1.4 Non-Applicability of Regulations of Concern

a. The affected chemical manufacturing units are not subject to the control requirements of 35 IAC 218 Subpart T, because, pursuant to 35 IAC 218.480(a), the rules of 35 IAC 218 Subpart T, Pharmaceutical Manufacturing, except for 35 IAC 218.483 through 218.485, apply to all emission units of VOM, including but not limited to reactors, distillation units, dryers, storage tanks for VOL, equipment for the transfer of VOL, filters, crystallizers, washers, laboratory hoods, pharmaceutical coating operations, mixing operations and centrifuges used in

manufacturing, including packaging, of pharmaceuticals, and emitting more than 6.8 kg/day (15 lb/day) and more than 2,268 kg/year (2.5 tons/year) of VOM. If such an emission unit emits less than 2,268 kg/year (2.5 tons/year) of VOM, the requirements of 35 IAC 218 Subpart T still apply to the emission unit if VOM emissions from the emission unit exceed 45.4 kg/day (100 lb/day).

b. The affected chemical manufacturing units are not subject to the control requirements of 35 IAC 218.501, Control Requirements for Batch Operations, pursuant to 35 IAC 218.501(b)(2), which excludes any emission unit included within the category specified in 35 IAC 218 Subpart T.

c. The affected chemical manufacturing units are not subject to 35 IAC 212.324, Process Emission Units In Certain Areas, because the source is not located in a non-attainment area for PM_{10}, as identified in 35 IAC 212.324(a)(1).

1.1.5 Operational and Production Limits and Work Practices

a. The owner or operator of a pharmaceutical manufacturing source shall repair any component from which a leak of VOL can be observed. The repair shall be completed as soon as practicable but no later than 15 days after the leak is found. If the leaking component cannot be repaired until the process unit is shut down, the leaking component must then be repaired before the unit is restarted [35 IAC 218.485].

b. The Permittee shall follow good operating practices for the scrubbers, condensers, steam jets, cyclones, vacuum pumps, surge tanks, and dust collectors including periodic inspection, routine maintenance and prompt repair of defects.

c. The affected chemical manufacturing units are not restricted to using the specific air control equipment listed in Condition 1.1.2, so long as emissions are kept below the applicable limits specified in Conditions 1.1.3, and 1.1.6.

1.1.6 Emission Limitations

In addition to Condition 5.2.2 and the source wide emission limitations in Condition 5.5 of the sources Title V permit, the affected chemical manufacturing units are subject to the following:

a. This permit is issued based on emissions of volatile organic material (VOM) from the new 1,500-gallon reactor PC-830 not exceeding 167 lbs/month and 0.5 ton/yr.

b. Compliance with annual limits shall be determined on a monthly basis from the sum of the data for the current month plus the preceding 11 months (running 12 month total).

c. This permit is issued based upon this project not constituting a major modification in accordance with 35 IAC 203, New Source Review (NSR). Maximum potential emissions from the affected equipment is less than significant net emission increase. (See attachment 1)

1.1.7 Testing Requirements

a. Upon request by the Illinois EPA or the USEPA, the owner or operator of any VOM source subject to 35 IAC 218 Subpart T or exempt from 35 IAC 218 Subpart T by virtue of the provisions of Condition 1.1.4(a) (See also 35 IAC 218.480), at his own expense, demonstrate compliance to the Illinois EPA and the USEPA by the methods or procedures listed in Condition 1.1.7 (d)(i)(A) (See also 35 IAC 218.105(f)(1)) [35 IAC 218.487].

b. Pursuant to 35 IAC 218.105(d)(1) and Section 39.5(7)(b) of the Act, the control device efficiency shall be determined by simultaneously measuring the inlet and outlet gas phase VOM concentrations and gas volumetric flow rates in accordance with the gas phase test methods specified below (See also 35 IAC 218.105(f)):

i. Volatile Organic Material Gas Phase Source Test Methods. The methods in 40 CFR Part 60, Appendix A, delineated below shall be used to determine control device efficiencies [35 IAC 218.105(f)].

A. CFR Part 60, Appendix A, Method 18, 25 or 25A, as appropriate to the conditions at the site, shall be used to determine VOM concentration. Method selection shall be based on consideration of the diversity of organic species present and their total concentration and on consideration of the potential presence of interfering gases. The test shall consist of three separate runs, each lasting a minimum of

60 min, unless the Illinois EPA and the USEPA determine that process variables dictate shorter sampling times [35 IAC 218.105(f)(1)].

B. 40 CFR Part 60, Appendix A, Method 1 or 1A shall be used for sample and velocity traverses [35 IAC 218.105(f)(2)].

C. 40 CFR Part 60, Appendix A, Method 2, 2A, 2C or 2D shall be used for velocity and volumetric flow rates [35 IAC 218.105(f)(3)].

D. 40 CFR Part 60, Appendix A, Method 3 shall be used for gas analysis [35 IAC 218.105(f)(4)].

E. 40 CFR Part 60, Appendix A, Method 4 shall be used for stack gas moisture [35 IAC 218.105(f)(5)].

F. 40 CFR Part 60, Appendix A, Methods 2, 2A, 2C, 2D, 3 and 4 shall be performed, as applicable, at least twice during each test run [35 IAC 218.105(f)(6)].

G. Use of an adaptation to any of the test methods specified in Conditions 1.1.7 (d)(i)(A), (B), (C), (D), (E) and (F) (See also 35 IAC 218.105(f)(1), (2), (3), (4), (5) and (6)) may not be used unless approved by the Illinois EPA and the USEPA on a case by case basis. An owner or operator must submit sufficient documentation for the Illinois EPA and the USEPA to find that the test methods specified in Conditions 1.1.7(d)(i)(A), (B), (C), (D), (E) and (F) (See also 35 IAC 218.105(f)(1), (2), (3), (4), (5) and (6)) will yield inaccurate results and that the proposed adaptation is appropriate [35 IAC 218.105(f)(7)].

ii. Notwithstanding other requirements of 35 IAC Part 218, upon request of the Illinois EPA where it is necessary to demonstrate compliance, an owner or operator of an emission unit which is subject to 35 IAC Part 218 shall, at his own expense, conduct tests in accordance with the applicable test methods and procedures specific in 35 IAC Part 218. Nothing in this Condition (See also 35 IAC

218.105) shall limit the authority of the USEPA pursuant to the Clean Air Act, as amended, to require testing [35 IAC 218.105(i)].

1.1.8 Monitoring Requirements

a. The owner or operator of any existing, new, or reconstructed affected source shall provide evidence of continued compliance with the standard as specified in 40 CFR Subpart GGG.

b. *Monitoring for Control Devices*.

i. *Parameters to Monitor*. For each control device, the owner or operator shall install and operate monitoring devices and operate within the established parameter levels to ensure continued compliance with the standard. Monitoring parameters are specified for control scenarios in 40 CFR 63 Subpart GGG

1.1.9 Recordkeeping Requirements

The Permittee shall maintain records of the following items for each affected chemical manufacturing unit to demonstrate compliance with Conditions 1.1.3, 1.1.5, and 1.1.6, pursuant to Section 39.5(7)(b) of the Act:

a. *Records of Operating Scenarios*. The owner or operator of an affected source shall keep records of each operating scenario which demonstrates compliance with 40 CFR 63 Subpart GGG [40 CFR 63.1259(c)].

b. Records of the testing of the efficiency of each capture system and control device pursuant to Condition 1.1.7, which include the following [Section 39.5(7)(e) of the Act]:

i. The date, place and time of sampling or measurements;

ii. The date(s) analyses were performed;

iii. The company or entity that performed the analyses;

iv. The analytical techniques or methods used;

v. The results of such analyses; and

vi. The operating conditions as existing at the time of sampling or measurement.

c. Pursuant to 35 IAC 218.489(b), for any leak subject to Condition 1.1.5(b) (See also 35 IAC 218.485) which cannot be readily repaired within one hour after detection, the following records shall be kept:

   i. The name of the leaking equipment [35 IAC 218.489(b)(1)];

   ii. The date and time the leak is detected [35 IAC 218.489(b)(2)];

   iii. The action taken to repair the leak [35 IAC 218.489(b)(3)]; and

   iv. The date and time the leak is repaired [35 IAC 218.489(b)(4)].

d. Pursuant to 35 IAC 218.489(c), the following records shall be kept for emission units subject to Condition 1.1.5(a) (See also 35 IAC 218.484) which contain VOL:

   i. For maintenance and inspection:

      A. The date and time each cover is opened [35 IAC 218.489(c)(1)(A)];

      B. The length of time the cover remains open [35 IAC 218.489(c)(1)(B)]; and

      C. The reason why the cover is opened [35 IAC 218.489(c)(1)(C)].

   ii. For production and sampling, detailed written procedures or manufacturing directions specifying the circumstances under which covers may be opened and the procedures for opening covers [35 IAC 218.489(c)(2)].

e. Pursuant to 35 IAC 218.489(d), for each emission unit used in the manufacture of pharmaceuticals for which the owner or operator of a pharmaceutical manufacturing source claims emission standards are not applicable, because the emissions are below the applicability cutoffs in Condition 1.1.4(a) (See also 35 IAC 218.480(a)), the owner or operator shall:

   i. Maintain a demonstration including detailed engineering calculations of the maximum daily and annual emissions for each such emission unit showing that the emissions are below the applicability cutoffs in Condition 1.1.4(a) (See also 35 IAC 218.480(a)) for the current

and prior calendar years [35 IAC 218.489(d)(1)]; and

ii. Maintain appropriate operating records for each such emission source to identify whether the applicability cutoffs in Condition 1.1.4(a) (See also 35 IAC 218.480(a)) are ever exceeded [35 IAC 218.489(d)(2)].

f. Copies of the records shall be made available to the Illinois EPA or the USEPA upon verbal or written request [35 IAC 218.489(f)].

g. The Permittee shall keep the following records for each product manufactured using the affected chemical manufacturing units. These records shall follow established techniques to calculate emissions:

i. A listing of the raw materials, process materials and associated air pollution control equipment used in making each product manufactured using affected chemical manufacturing units;

ii. A demonstration including engineering calculations for the HAP, PM, and VOM emissions generated for each process per batch of each product manufactured using affected chemical manufacturing units;

iii. A demonstration including engineering calculations for the HAP, PM, and VOM control efficiencies of air pollution control equipment, if any, and emissions to the atmosphere for any air pollution control equipment operating in a normal manner. This demonstration shall also show compliance with the control requirements of 35 IAC 218 Subpart T, if applicable to any of the affected chemical manufacturing units;

iv. The operating parameters of air pollution control equipment, if any, when operating normally (e.g., temperature of condenser cooling water supply); and

v. Methodologies for recalculating emissions from batches run during the malfunction of control equipment.

h. The Permittee shall keep the following records on a batch basis:

i. Records to show that air pollution control equipment is operated in a normal manner, as specified by the above records for a particular product manufactured using affected chemical manufacturing units;

ii. Records of the number and size of batches run for each product manufactured using affected chemical manufacturing units. For this purpose, a batch shall be considered to run on the day the batch is initiated. Any batch terminated prematurely will be assumed to be a completed batch; and

iii. Records of the times and duration of any malfunction in any air pollution control equipment.

i. The Permittee shall keep the following records on a monthly basis, prepared by the 15th day of the following month:

i. Records of HAP, PM, and VOM emissions for each product manufactured using affected chemical manufacturing units in the month, determined by combining the above records for generated emissions, control efficiency (if control operated in a normal manner) and production rate;

ii. Records of HAP, PM, and VOM emissions for the month for each batch made using affected chemical manufacturing units during any malfunction of air pollution control equipment; and

iii. Records of the aggregate annual HAP, PM, and VOM emissions from the affected chemical manufacturing units for each month, determined from the sum of the current month's emissions and the emissions from the previous 11 months.

j. The Permittee shall maintain an On-Site Implementation Log (OSIL) which shall contain the following information with respect to the equipment changes authorized by Conditions 1.1.11(b) and (c):

i. Name and location of batch process with replacement component(s) or control device(s);

ii. Description of the component(s) or control device(s) replaced;

iii. Asset or identification number of replacement component(s) or control device(s);

iv. The effective size or capacity of the original and each replacement component;

v. The effective efficiencies of the original control device(s) and the replacement control device(s);

vi. Manufacturer(s) and model number(s) of the replacement component(s) or control device(s);

vii. The date of installation of the replacement component(s) or control device(s); and

viii. Other information as needed to show the change is within the scope of Condition 1.1.11(b) or (c).

1.1.10 Reporting Requirements

The Permittee shall promptly notify the Illinois EPA, Compliance Section of noncompliance of an affected chemical manufacturing unit with the permit requirements as follows, pursuant to Section 39.5(7)(f)(ii) of the Act. Reports shall describe the probable cause of such deviations, and any corrective actions or preventive measures taken:

a. A person planning to conduct a VOM emissions test to demonstrate compliance with 35 IAC 218 Subpart T shall notify the Illinois EPA and the USEPA of that intent not less than 30 calendar days before the planned initiation of the test [35 IAC 218.487(b)].

b. For each emission unit used in the manufacture of pharmaceuticals for which the owner or operator of a pharmaceutical manufacturing source claims emission standards are not applicable, because the emissions are below the applicability cutoffs in Condition 1.1.4(a) (See also 35 IAC 218.480(a)), the owner or operator shall provide written notification to the Illinois EPA and the USEPA within 30 days of a determination that such an emission unit has exceeded the applicability cutoffs in Condition 1.1.4(a) (See also 35 IAC 218.480(a)) [35 IAC 218.489(d)(3)].

c. Emissions of PM and/or VOM in excess of the limits in Conditions 1.1.3 and/or 1.1.6 based on the current month's records plus the preceding 11 months within 30 days of such an occurrence.

1.1.11 Operational Flexibility/Anticipated Operating Scenarios

The Permittee is authorized to make the following changes with respect to the affected chemical manufacturing units without prior notification to the Illinois EPA or revision of this permit. This condition does not affect the Permittee's obligation to properly obtain a construction permit in a timely manner for any activity constituting construction or modification pursuant to regulations promulgated pursuant to Title I of the CAA (i.e., 40 CFR 52.21 and 35 IAC Part 203):

a. This permit is issued for production of pharmaceuticals, chemical intermediates for pharmaceutical products and pharmaceutical-like products such as hormones, enzymes and antibiotics. In addition to varying the quantities of such materials produced, the Permittee may change the types of such materials produced, making products not previously made in the affected chemical manufacturing units, or changing the process by which such materials are made, provided that Conditions 1.1.3, or 1.1.6 are not violated.

b. The replacement of component parts for a batch process with the same or functionally similar component parts, provided there is no effective increase in the capacity of the batch process (i.e., like-kind replacement), provided that the replacements are not so extensive as to constitute reconstruction of the batch process and it can be demonstrated that emissions from the batch process remain in compliance with the limits specified in Conditions 1.1.3, and 1.1.6 (e.g., reactor).

c. The replacement of control devices with control devices with the same or better effective efficiency, provided there is no increase in emissions over the limits specified in Conditions 1.1.3, and 1.1.6 (e.g., condenser).

1.1.12 Compliance Procedures

Compliance with the emission limits shall be based on the recordkeeping requirements in Condition 1.1.9 and the emission factors and formulas listed below:

a. Determinations of daily and annual emissions for purposes of Condition 1.1.4(a) (See also 35 IAC 218.480) shall be made using both data on the hourly emission rate (or the emissions per unit of throughput) and appropriate daily and annual data from records of emission unit operation (or material

throughput or material consumption data). In the absence of representative test data pursuant to Condition 1.1.7(c) (See also 35 IAC 218.487) for the hourly emission rate (or the emissions per unit of throughput) such items shall be calculated using engineering calculations, including the methods described in Appendix B of "Control of Volatile Organic Emissions from Manufacturing of Synthesized Pharmaceutical Products" (EPA-450/2-78-029). This Condition shall not affect the Illinois EPA's or the USEPA's authority to require emission tests to be performed pursuant to Condition 1.1.7(c) (See also 35 IAC 218.487)) [35 IAC 218.480(h)].

b. Compliance with Conditions 1.1.3(b), and (d) is assumed by proper operation of the control equipment.

c. To determine compliance with Conditions 1.1.3, and 1.1.6, VOM emissions from the affected chemical manufacturing units calculations based on the formulas and procedures listed in either Appendix B of "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products" (EPA-450/2-78-029) or "Control of Volatile Organic Compound Emissions from Batch Processes-Alternative Control Techniques Information Document" (EPA-450/R-94-020) are acceptable.

Please note this permit has been revised to allow the source one additional year to commence construction.

If you have any questions on this, please call Kevin Smith at 217/782-2113.

Donald E. Sutton, P.E.
Manager, Permit Section
Division of Air Pollution Control

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cc: Region 1

Attachment 1

NSR Applicability

Table I – Permitted VOM Emissions Increases Associated With The Proposed Modifications

Item of Equipment	Install Date	Emission Increases (Tons/Year)
New PC 830	2/02	0.5

Table II – Source-Wide Creditable Contemporaneous VOM Emission Decreases (Tons/Year)

Item of Equipment	Removal/Reduction Date	Emission Decreases
Existing PC830	1/02	0.1275

Table IV – Net VOM Emissions Change (Tons/Year)

Table I	0.5
Table II	- 0.1275
Totals:	0.3725

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